



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4848]

Human Factors Studies and Related Clinical Study Considerations in Combination Product

Design and Development; Draft Guidance for Industry and Food and Drug Administration Staff;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and FDA staff entitled "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." This document provides guidance to industry and FDA staff on the underlying principles of human factors (HF) studies during the development of combination products. Combination products are comprised of any combination of a drug and a device; a device and a biological product; a biological product and a drug; or a drug, a device, and a biological product.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-D-4848 for "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, Bldg. 32, rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Love, Deputy Director, Office of Combination Products, Office of Special Medical Programs, Office of Medical Products and Tobacco, Office of the Commissioner, Food and Drug Administration, at patricia.love@fda.hhs.gov or 301-796-8933.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." This document provides guidance to industry and FDA staff on the underlying principles of HF studies during the development of combination products as defined under 21 CFR part 3. This draft guidance describes Agency recommendations regarding HF

information in a combination product investigational or marketing application. It clarifies the different types of HF studies, offers recommendations for timing and sequencing of HF studies, and discusses how HF studies contribute to assuring that combination products are safe and effective for the intended users, uses and environments. The draft guidance also addresses process considerations for HF information in investigational or marketing applications to promote development and timely review of safe and effective combination products. In addition, the draft guidance describes how HF studies relate to other clinical studies.

This draft guidance refers to two existing guidance documents that provide related information on HF considerations. These are Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Optimize Medical Device Design," accessible at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259760.pdf> and Draft Guidance "Safety Considerations for Product Design to Minimize Medication Errors," accessible at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM331810.pdf>.

This draft guidance provides examples of the use of HF studies for different types of combination products in different clinical settings. FDA welcomes comments to the docket on other examples of combination products and why they may or may not need HF studies. Additionally FDA seeks comments on what challenges and development risks may arise depending upon whether HF studies are conducted before, in parallel to, or after major clinical studies.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122047.htm>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 314 for NDAs and ANDAs have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910-0338. The collections of information in 21 CFR part 814, subparts B and E, for PMAs have been approved under OMB control number 0910-0231. The collections of information in 21 CFR part 814, subpart H, for humanitarian device exemption applications have been approved under OMB control number 0910-0332. The collections of information in 21 CFR part 807, subpart E, for 510(k) notifications have been

approved under OMB control number 0901-0120. The collections of information in 21 CFR part 312 for INDs have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 812 for IDEs have been approved under OMB control number 0910-0078. The collections of information in 21 CFR part 820 for the quality system regulation have been approved under OMB control number 0910-0073.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy

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